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09/902,174	07/10/2001	Inga Laursen	0459-0636P	8992

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EXAMINER	
SAUNDERS, DAVID A	

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3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 902,174	Applicant(s) LAURSEN et al
	Examiner SAUNDERS	Group Art Unit 1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-12 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) 1-12 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

The claims pending and under examination are 1-12.

At specification page 1 the status of parent application 09/328,497 must be updated.

Claims 1-2 and 11-12 are objected to because of the following informalities: In claim 1, part (j) --agent-- has been misspelled. Appropriate correction is required.

Claims 1-2, 9 and 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, part (b) the phrase "such as" renders the claim indefinite for the reason that it is unclear whether the limitations following the phrase are part of the claimed invention. MPEP 2173.05 (d).

In claim 9 recitation of "for use in medicine" is unclear because it is not clear what additional feature would render the product of claim 3 to be suitable for such a use. The disclosure has indicated that the product of claim 3 per se would be suitable for such a use.

Further, claim 9 is unclear by reciting "for use" because it is not clear if applicant is intending to claim a product or a method.

Claim 9 provides for the use of a product, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

> (f) he did not himself invent the subject matter sought to be patented.

Claims 1-2 and 11-12 are rejected under 35 U.S.C. 102(b) as being entirely anticipated by applicant's admitted state of the art regarding the Octagam liquid formulation and/or any of Mollnes et al., Brenner or Biesert.

Applicant has admitted in Example 2 (espec. Table and last para. therein) that Octagam is a known liquid formulation of IgG. In the last para. (Page 30, line 33 - page 31, line 4) applicant refers to "the other liquid product analyzed", which must be Octagam according to the Table. Applicant admits that for this other product and applicant's product "their formulations appear very similar". From the Table (page 26) the examiner notes that Octagam and IVIG, SSI (applicant's product) are indistinguishable in terms of purity, in content of monomers and dimers, in terms of PEG content, and in terms of saccharide content. The examiner makes this determination based upon the most lenient limits for these parameters contemplated by applicant is the disclosure --espec. at pages 19-22. Applicant considers that the content of polymers and aggregates distinguishes the instant product from the other liquid formulation (page 31, lines 1-4). This content is not recited as a feature of the rejected claims.

In addition to applicant's admissions, the publications of Mollnes et al., Brenner, and Biesert are taken as evidence that Octagam was known and was available for sale more than one year prior to applicant's date of filing provisional application 60/102,055. Though Mollnes et al's publication date, is within a year thereof, the submission date of the article is prior to one year. This date is taken as evidence that the Octagam was available more than one year before

the filing of the provisional application, since the product must have been obtained before the article would have been submitted.

With respect to the treatment method claims 11-12, applicant has admitted (pages 2-3) that it was known to are IVIG preparations for treating conditions encompassed by the claims, and it is considered that such use would have been immediately apparent to one of skill given the availability of the Octagam product. Also note that Brenner et al. use Octagam to treat ITP.

Claims 1-2 and 11-12 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. Applicant's admissions, at the above noted portions of the disclosure in the 102(b) rejection, are taken as evidence that applicant is not the inventor.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Doleschel et al. (4,880,913, cited on 1449).

As far as can be determined from applicant's disclosure (e.g. Table in Example 2 at page 26) and from the Tables of Doleschel et al. (lower row in each case), the instant preparations are not distinguished from those of Doleschel et al. in terms of purity, monomer/content and IgA content in instant claim 3.

Claim 4 is included since Doleschel et al.'s method of preparation dialyzes away all PEG.

Claim 6 is included because Doleschel et al. do not teach that their method isolates any particular IgG subclass. It is therefore considered that their product has the normal content of the four IgG subclasses corresponding to percentage ranges of claim 6.

Claims 7-10 are rejected, since Doleschel et al. teach intravenous administration in liquid form (title and col. 4, lines 16-20).

Claim 1 is included because it is considered, by virtue of applicant's disclosure, that the characteristics of the preparation of Doleschel et al. (Tables) would be inherent to a composition obtained by the method of instant claim 1. Regarding claim 2, note Doleschel et al. at col. 2, lines 42+.

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Mamidi et al. (6,162,904, cited on 892).

The examiner is relying upon portions of the Mamidi et al. disclosure that are common to application 08/977,972 filed 12/24/97. Applicant is referred to WO 99/33484 for a disclosure equivalent to that application.

Mamadi et al. teach (Tables showing test results for Examples 1 and 2) a product that is consistent with the limits of instant claim 3.

Claim 4 is rejected, since Mamidi et al. teach PEG and albumin are removed in the preparative process (col. 7, lines 1-10).

Claim 5 is included since the IgA content of 22 ug/ml (test results of Example 1) convert to 2.2 mg/L.

Claim 6 is rejected with the same rational applied supra to Doleschel et al.

Claims 7-10 are rejected since Mamidi et al. teach IV administration of a liquid product (e.g. col. 3, lines 33-35 and col. 9, lines 4-11).

Claims 1-2 are included in the rejection according to the same rational stated supra for Doleschel et al.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3 and 11-12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Doleschel et al. alone or in view of applicant's admissions.

Claims 1, 3 and 11-12 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mamidi et al., alone or in view of applicant's admissions.

Doleschel et al. and Mamidi et al. have noted supra regarding product claims. With respect to method claims these references do not specifically teach what the IgG preparation is used for. However it is taken that it was so well known to use such preparations for treating patients with various immunodeficiencies and infections that the recited uses would have been immediately envisioned (anticipation). Otherwise, for obviousness, applicant's review of the state of the art (pages 1-3) admits that it was known to uses intravenously administrable IgG preparations to treat conditions encompassed by the claims; hence, using the product of Doleschel et al. or of Mamidi et al. to treat such diseases would have been obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644

D. Saunders:jmr

November 15, 2002